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10/674,491	10/01/2003	Jean-Pascal Hirt	235016US26	4669

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EXAMINER	
FOREMAN, JONATHAN M	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
01/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/674,491	HIRT ET AL.	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,30,32,56 and 71-83* is/are pending in the application.

4a) Of the above claim(s) *2,3,14-16,21,23-29,46-48,53,55-70 and 72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-13,17-20,22,30,32-45,49-52,54,71 and 73-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4 – 6, 13, 17 – 20, 22 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al in view of. U.S. Patent No. 6,254,294 to Muhar.

In regard to claims 1, 4 – 6, 13, 17 – 20, 22 and 80, Zhang et al. discloses a plurality of applicators capable of containing different test substances (Col. 5, lines 20 – 25) each applicator comprising: a tube (40); a plug inside the tube (58); and at least one test substance (48) contained in an inside space of the tube defined at a first end by the plug, the plug being arranged, in use, to be expelled together with the test substance when said test substance leaves the inside space of the tube (Figure 3). Regarding claim 13, Zhang et al. disclose a tube, wherein the inside space is defined at a second end (46), remote from the first, by a breakable portion (42). With regard to claim 17, Zhang et al. discloses the applicator includes a retaining element for retaining the breakable portion on the applicator after it has been broken off (Figure 3, 42). In regards to claim 18, Zhang et al. disclose the tube (40)being provided at one end with an applicator element (72), the applicator element being separated from the test substance prior to use, by the plug (Figure 2, 58). With respect to claim 19, Zhang et al. disclose the applicator element (72) being selected from the group consisting of a cotton bud (Column 5, line 62 – Column 6, lines 3), a foam bud, a felt tip, a flocked bud, and a tip

made of ceramic or of sintered material. In respect to claim 20, Zhang et al. disclose the tube being free of an applicator element (Figure 1). Regarding claim 22, Zhang et al. disclose the plug comprises a liquid, and wherein said liquid is selected from the group consisting of mineral oils, fluorine-containing substances, and silicones (Column 5, lines 44 – 47). However, Zhang fails to disclose a housing having a plurality of applicators containing different substances. Muhar teach a kit having a housing with compartments for containing different test substances (40, 74). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a plurality of applicators each with a different test substance in a housing having compartments as taught by Muhar in order to create a treatment kit to raise the awareness of a treatment choice to a consumer (Col. 5, lines 47 – 56).

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al in view of. U.S. Patent No. 6,254,294 to Muhar as applied to claim 1 above, and further in view of Zygmont (US Patent No. 6,488,646).

In regard to claim 7, Zhang et al. in view of Muhar disclose all of the aforementioned elements. However, Zhang et al. in view of Muhar does not disclose at least one bag for packaging at least one applicator. Zygmont discloses one bag (2) for packaging at least one applicator (Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Zygmont to enclose a bag around an applicator with Zhang et al. in view of Muhar in order to keep each applicator sterile.

In regard to claim 8, Zhang et al. in view of Muhar and futher in view of Zygmont disclose the claimed invention except for a string of bags each containing at least one applicator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

incorporate a string of bags for each of the applicators, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 9 and 10, are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al in view of. U.S. Patent No. 6,254,294 to Muhar as applied to claim 1 above, and further in view of Barabino et al. (US Patent No. 4,740,194).

In regard to claims 9 and 10, Zhang et al. in view of Muhar disclose an applicator that is labeled (Column 2, lines 57-58). However, Zhang et al. does not disclose each applicator includes at least one mark corresponding to at least one of a type of test substance inside the tube and a concentration of a compound contained in the test substance. However, Barabino et al. discloses each applicator includes at least one mark comprising one of an alphanumeric symbol and a color corresponding to at least one of a type of test substance inside the tube and a concentration of a compound contained in the test substance (Column 6, lines 6-8). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Barabino et al. to include a marking on each applicator with Zhang et al. in view of Muhar in order to differentiate applicators and their respective content.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al in view of. U.S. Patent No. 6,254,294 to Muhar as applied to claim 1 above, and further in view of Tobin et al. (US Patent No. 3,792,699).

In regard to claims 11 and 12, Zhang et al. in view of Muhar disclose a kit, but fails to disclose the test substance in each tube having a volume in a range from 0.01 ml to 5 ml or 0.05 ml to 1 ml. Tobin et al., however, discloses a kit, wherein the tube has a volume in the range of 0.01 ml

to 5 ml or 0.05 ml to 1 ml (Column 3, lines 20-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made in view of Tobin et al. to modify the volume of the tubes as disclosed by Zhang et al. in view of Muhar to be the range from 0.01 ml to 5 ml or 0.05 ml to 1 ml in order to sufficiently moisten the applicator region and to provide an amount effective for treatment.

Claims 30, 32, 35 – 38, 45, 49 – 52, 54, 71, 73, 74, 76 and 81 - 83 rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of U.S. Patent No. 6,358,231 to Schindler et al.

In regard to claims 30 – 32, 35 – 38, 45, 49 – 52, 54, 71, 73, 74, 76 and 81 – 83, Zhang et al. disclose a plurality of applicators capable of containing different test substances (Col. 5, lines 20 – 25) each applicator comprising: a tube (40); a plug inside the tube (58); and at least one test substance (48) contained in an inside space of the tube defined at a first end by the plug, the plug being arranged, in use, to be expelled together with the test substance when said test substance leaves the inside space of the tube (Figure 3). Zhang et al. disclose a tube, wherein the inside space is defined at a second end (46), remote from the first, by a breakable portion (42). Zhang et al. disclose the applicator includes a retaining element for retaining the breakable portion on the applicator after it has been broken off (Figure 3, 42). Zhang et al. disclose the tube (40) bieng provided at one end with an applicator element (72), the applicator element being separated from the test substance prior to use, by the plug (Figure 2, 58). Zhang et al. disclose a kit, wherein the applicator element (72) is selected from the group consisting of a cotton bud (Column 5, line 62 – Column 6, lines 3), a foam bud, a felt tip, a flocked bud, and a tip made of ceramic or of sintered material. Zhang et al. disclose the tube is free of an applicator element (Figure 1). Zhang et al. disclose the plug comprises a liquid, and wherein said liquid is selected from the group consisting of

mineral oils, fluorine-containing substances, and silicones (Column 5, lines 44 – 47). Zhang et al. disclose at least three applicators having different test substances (Col. 5, lines 20 – 25) including pharmaceutical substances. However, Zhang et al. fails to disclose the pharmaceutical substances being at least two substances with at least one compound at concentrations varying by a factor of at least two from one to another nor a stimulating agent for stimulating a peripheral nervous system. Nor does Zhang et al. disclose packaging in which the applicators are housed. Schindler et al. discloses a kit having a plurality of applicators housed in a housing, wherein the housing includes at least one compartment configured to receive a single applicator or a plurality of applicators (Figure 7). Schindler et al. teach the use of at least two substances with at least one compound at concentrations varying by a factor of at least two from one to another, the substance being a stimulating agent for stimulating a peripheral nervous system (Col. 1, lines 58 – 63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the kit as disclosed by Zhang et al. to include a packaging having compartments as taught by Schindler et al. in order to keep the applicators sterile and from moving around during transport. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the substances as disclosed by Zhang et al. to include a stimulating agent in varying concentrations as taught by Schindler et al. in order to anesthetize the eye, mouth or ear of a patient as needed. (Col. 1, lines 45 – 67).

Claims 39, 40 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of U.S. Patent No. 6,358,231 to Schindler et al. as applied to claims 30 and 71 above, and further in view of Zygmont (US Patent No. 6,488,646).

In regard to claims 39 and 77, Zhang et al. in view of Schindler et al. discloses a packaging for at least one applicator. However, Zhang et al. in view of Schindler et al. does not disclose at least one bag for packaging at least one applicator. Zygmont discloses one bag (2) for packaging at least one applicator (Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Zygmont to enclose a bag around an applicator with Zhang et al. in view of Schindler et al. in order to keep each applicator sterile.

In regard to claim 40, Zhang et al. in view of Schindler et al. and further in view of Zygmont discloses the claimed invention except for a string of bags each containing at least one applicator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a string of bags for each of the applicators, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 41 and 42, are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of U.S. Patent No. 6,358,231 to Schindler et al. as applied to claim 30 above, and further in view of Barabino et al. (US Patent No. 4,740,194).

In regard to claims 41 and 42, Zhang et al. in view of Schindler et al. disclose an applicator that is labeled (Column 2, lines 57-58). However, Zhang et al. in view of Schindler et al. does not disclose each applicator includes at least one mark corresponding to at least one of a type of test substance inside the tube and a concentration of a compound contained in the test substance. However, Barabino et al. discloses each applicator includes at least one mark comprising one of an alphanumeric symbol and a color corresponding to at least one of a type of test substance inside the tube and a concentration of a compound contained in the test substance (Column 6, lines 6-8). It

would have been obvious to one having ordinary skill in the art at the time the invention in view of Barabino et al. to include a marking on each applicator with Zhang et al. in view of Schindler et al. in order to differentiate applicators and their respective content.

Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of U.S. Patent No. 6,358,231 to Schindler et al. as applied to claim 30 above , and further in view of Tobin et al. (US Patent No. 3,792,699).

In regard to claims 43 and 44, Zhang et al. in view of Schindler et al. fails to disclose the substance in each tube having a volume in a range from 0.01 ml to 5 ml or 0.05 ml to 1 ml. Tobin et al., however, discloses a kit, wherein the tube has a volume in the range of 0.01 ml to 5 ml or 0.05 ml to 1 ml (Column 3, lines 20-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made in view of Tobin et al. to modify the volume of the tubes as disclosed by Zhang et al. in view of Schindler et al. to be the range from 0.01 ml to 5 ml or 0.05 ml to 1 ml in order to sufficiently moisten the applicator region.

Claims 32 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of U.S. Patent No. 6,358,231 to Schindler et al. as applied to claim 30 above, and further in view of Barr et al. (US Patent No. 6,812,254).

In regard to claims 32 - 35, Zhang et al. in view of Schindler et al. disclose a plurality of applicators containing different test substances (Col. 5, lines 20 – 25) each applicator comprising: a tube (40); a plug inside the tube (58); and at least one test substance (48) contained in an inside space of the tube defined at a first end by the plug, the plug being arranged, in use, to be expelled together with the test substance when said test substance leaves the inside space of the tube (Figure 3). Zhang et al. in view of Schindler disclose a kit capable of comprising pharmaceutical products

(Abstract). Barr et al. discloses a kit comprising at least two test substances with a substance capable of being at varying concentrations (Column 3, lines 44-65 & Column 7, line 40 – Column 8, line 38). The substances include a stimulating agent for stimulating a peripheral nervous system (Abstract & Column 4, lines 5-23). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Barr et al. to have different test substances with varying concentrations with Zhang et al. in view of Schindler et al. in order to administer varying levels of treatment for pains and discomforts (Column 1, lines 6 – 12). The stimulating agent for stimulating the peripheral nervous system is selected from the group consisting of natural or synthetic capsaicinoids, homocapsaicin, homodihydrocapsaicin, nordihydrocapsaicin, dihydrocapsaicin; lactic acid, glycolic acid, ethanol at a concentration greater than 50%, mustard seed oil (Barr et al., Column 3, lines 14-18). A concentration of the stimulating agent for stimulating the peripheral nervous system lies in a range from 10-6% to 10-2% by weight (Barr et al., Column 3, lines 45-65).

Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of U.S. Patent No. 6,358,231 to Schindler et al. as applied to claim 71 above, and further in view of Lewis and further in view of Ohsumi (US Patent No. 5,658,981).

In regard to claim 75, Zhang et al. in view of Schindler et al. fail to disclose each tube further comprises a thermoreversible thickener inside the volume. Ohsumi, however, teaches the use of thermoreversible thickener (Abstract & Column 1, lines 43-52). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Ohsumi to add thermoreversible thickener to the volume with Zhang et al. in view of Schindler et al. in order to control aqueous solutions, which thicken rapidly within a narrow temperature range (Column 1, lines 43-52).

Claims 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view

of U.S. Patent No. 6,358,231 to Schindler et al. as applied to claim 71 above, and further in view of Lewis (US Patent No. 5,947,986).

In regard to claims 78 and 79, Zhang et al. in view of Schindler et al. disclose a packaging, but fail to disclose the packaging having a stand; a body mounted on the stand and a closure cap coupled to the body of the portions of tubes extending outside the body. However, Lewis discloses a packaging including a stand (Lewis, 52); and a body (Lewis, 56) mounted on said stand. Each tube in the packaging (Lewis, 12) has a portion extending outside said body (Lewis, 56), and a closure cap (Lewis, 60) coupled to said body and over said portions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the packaging as disclosed by Zhang et al. in view of Schindler et al. to include a body, stand and cap as taught by Lewis in order to make the tubes more easily accessed by the user.

Response to Arguments

Applicant's arguments filed 11/1/07 have been fully considered but they are not persuasive. Applicant asserts that Schindler et al. fails to teach injecting devices including test substances with at least one compound at different concentrations. However, teh Examiner disagrees. Schindler et al. teach the use of at least two substances with at least one compound at concentrations varying by a factor of at least two from one to another, the substance being a stimulating agent for stimulating a peripheral nervous system (Col. 1, lines 58 – 63).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMLF

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